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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,898	02/17/2000	Kirti Dave	065733/2262	7146

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/08/2002

SA

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/505,898

Applicant(s)

DAVE ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-62 is/are pending in the application.
- 4a) Of the above claim(s) 48-53 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-47, 54-56, 60-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed February 4, 2002 (Paper No. 23) in response to the Office Action of December 12, 2001 is acknowledged and has been entered. Claims 44-62 are pending. Claims 48-53 and 57-59 are withdrawn from consideration as these claims would have been subject to an Election/Restriction requirement. Therefore, claims 44-47, 54-56 and 60-62 represent group I and are currently examined.

The newly added claims 48-53 and 57-59 are grouped in the following way

- II. Claims 44 and 48-53, drawn to method of analyzing arthropods for the presence of togaviruses, classified in class 424, subclass 217.1.
- III. Claims 44 and 57-59, drawn to a method of analyzing arthropods for the presence of malaria, classified in class 424, subclass 268.1.

Group II of this application contains claims directed to the following patentably distinct species of the claimed invention:

- A- hemorrhagic fever virus (Dengue virus, West Nile Virus) -
- B- encephalitis virus (St. Louis Encephalitis Virus, Western Equine Virus, Eastern Equine Virus)

Claim 44 links inventions of groups II and III. The restriction requirement of the linked inventions is subject to the nonallowance of the linking claim, claim 44. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim

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is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The rejection of claim 44 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of applicants amendment.

The rejection of claim 44 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of applicants amendments.

The rejection of claim 44 and newly added claims 45, 46, 54-56 and 60-62 under 35 U.S.C. 103(a) as being unpatentable over Oprandy et al. (Journal of Clinical Microbiology, 1990, from applicant's IDS) in view of Huang et al. (U.S.Pat. No. 5,712,172) **is maintained** for reasons of record.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

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combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Huang et al disclose a method of making and producing a lateral flow device that is able to detect an analyte in a sample, the reference teaches a specific embodiment that of analyzing the urine analyte sample, however the claims are broadly drawn to any liquid sample; "the term sample as used herein refers to any biological sample that could contain an analyte for detection. Preferably the biological sample is in liquid form or can be changed into a liquid form (column 4 lines 63-67)." Therefore, applicant incorrectly concludes that the reference only contemplates urine samples. The reference teaches a method of setting up the test strip and also using the appropriate controls, utilizing colored detection agent. The test strip uses wicking action to pass the liquid over the various zoned containing analyte detection reagent and capture reagent. While the Oprandy et al. reference teaches that mosquito agents can be detected from ground up mosquitoes that utilize a grinding solution to expose the analyte using an antibody. Antibody-antigen (analyte) reactions are well known and well understood in the art. Changing the assay format from a dot-blot to a capture assay such as an ELISA or an affinity assay is interchangeable because these assays all depend on the unique antibody-antigen interaction. It is

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the antibody-antigen interaction that may provide unique and unusual properties and not the matrix to which the assay is attached. Therefore, the rejection is maintained.

The rejection of claim 44 and newly added claims 45-47, 54-56 and 60-62 under 35 U.S.C. 103(a) as being unpatentable over Oprandy et al. (Journal of Clinical Microbiology, 1990, from applicant's IDS) and Huang et al. (U.S.Pat. No. 5,712,172) in view of Rattanarithikuln et al. (American Journal of Tropical Medicine, 1996, from applicant's IDS) and Sithiprasasna et al. (Annals of Tropical Medicine and Parasitology, from applicant's IDS).

The relevance of Oprandy et al. and Huang has been discussed above and in the prior office action. The newly added claims include a method whereby multiple analyte specific capture reagents are used in a single assay. The references of Rattanarithikuln et al. and Sithiprasasna et al. both teach ELISA capture assay for different analyte samples found in mosquitoes, specifically against antigens of malaria and dengue. Both references teach utilizing multiple monoclonal antibodies to different species of parasite or viral strains.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the antibody detection reagents as taught by Oprandy et al., Rattanarithikuln et al. and Sithiprasana et al. and apply them to the lateral flow device taught by Huang et al. which has the advantage of detecting an analyte from a biological sample in a single step. One having ordinary skill in the art would have been motivated to do this because in order to determine the risk of arthropod-vector disease spread it is necessary to survey the insect population for the etiologic agent. This information is important to assess the efficacy of insect control and abatement programs. One having ordinary skill in the art would have a high

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expectation of success in applying the antibodies and the methods of exposing the antigens using detergents. Therefore, the instant invention is obvious over Oprandy et al. and Huang et al. in view of Rattanarithikuln et al. and Sithiprasasna et al.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Ulrike Winkler, Ph.D.


JEFFREY STUCKER
PRIMARY EXAMINER